

PRELIMINARY AMENDMENT

U.S. Appln. No. Not Yet Assigned

- about*
- (iv) spraying said coating liquid onto said fluidized bed from beneath the fluidized bed to coat said microparticles with said coating liquid under saturated moisture conditions; and
  - (v) allowing the resulting coated microparticles to dry.

Claim 2. (Amended) The method according to claim 1, additionally comprising one or more additional coating steps to further coat the microparticles with at least one of an enteric coating, a film coating, a moisture repellant coating, and a taste-masking coating.

Claim 3. (Amended) The method according to claim 1, wherein in step (v) the resulting microparticles are heat dried.

Claim 4. (Amended) The method according to claim 1, wherein the active ingredient comprises one or more proteins, peptides or cells.

Claim 5. (Amended) The method according to claim 1, wherein the water soluble/miscible solvent is glycerol, propylene glycol, or a combination of glycerol and propylene.

Claim 6. (Amended) The method according to claim 1, wherein the sugar polymer is selected from the group consisting of dextran, fructose, fruitose, glucose, invert sugar, lactitol, lactose, maltitol, maltodextrin, maltose, mannitol, sorbitol, sucrose, trehalose, isomalt, xylitol and polydextrose, or a combination thereof.

Claim 7. (Amended) The method according to claim 1, wherein the water soluble gel forming solid particles comprise a member selected from the group consisting of acrylate or

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Abstract.  
derivatives thereof, albumin, alginates, carbomers, carrageenan, cellulose or derivatives thereof, dextran, dextrin, gelatine, polyvinylpyrrolidone and starch.

Claim 8. (Amended) The method according to claim 1, wherein the method is conducted in a moisture saturated environment.

Claim 9. (Amended) The method according to claim 1, wherein the method is conducted in an oxygen free environment.

Claim 10. (Amended) The method according to claim 1, wherein the resulting coated microparticles are formed into a composition for injection, as a sublingual tablet, as an oral tablet, as a sustained release sublingual tablet, into microcapsules, pessaries, preconstituted solid dose for nasal spray, nasal drops, aqueous drops, eye wash, eye drops, skin washing solutions or as a feed premix.

Claim 11. (Amended) The method according to claim 1, wherein said method is useful for stabilizing biologically active ingredients.

Claim 12. (Amended) The method according to claim 1, wherein the microparticles have a particle size of 50 microns to one millimeter.

Claim 13. (Amended) The method according to claim 1, wherein the active ingredient is a hormone, cytokine or growth factor or a combination of any two or more thereof.

Claim 14. (Amended) The method according to claim 13, wherein the active ingredient is selected from the group consisting of a human growth hormone, an animal growth hormone, a human growth hormone derivative, an animal growth hormone

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derivative, erythropoietin, calcitonin, interferon, interleukin, insulin and a colony stimulating factor.

Claim 15. (Amended) The method according to claim 1, wherein the active ingredient is an enzyme.

Claim 16. (Amended) The method according to claim 15, wherein the enzyme is selected from the group consisting of streptokinase, muramidase, pancrease, amylase, protease, lypase, cellulase, bromelain and papain.

Claim 17. (Amended) The method according to claim 1, wherein the active ingredient is glucan.

Claim 18. (Amended) The method according to claim 17, wherein said glucan is  $\beta$ -1,3-glucan.

Claim 19. (Amended) The method according to claim 1, wherein the active ingredient is a microorganism.

Claim 20. (Amended) The method according to claim 19, wherein the microorganism is one or more of *Bifidus* or *Lactobacilli*.

Claim 21. (Amended) A product produced by the method according to any one of claims 1 to 20.

Claim 22. (Amended) A composition comprising a core of microparticles coated with a moisture-sensitive biologically active ingredient and sugar polymer coating layer.

Claim 23. (Amended) The composition according to claim 22, wherein said microparticles are further coated with at least one of an enteric coating, a film coating, a moisture repellent coating and a taste-masking coating.

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Claim 24. (Amended) The composition according to claim 22, wherein the active ingredient comprises one or more proteins, peptides or cells.

Claim 25. (Amended) The composition according to claim 24, wherein the active ingredient is a hormone, cytokine, or growth hormone, or a combination of any two or more thereof.

Claim 26. (Amended) The composition according to claim 25, wherein the active ingredient is selected from the group consisting of a human growth hormone, an animal growth hormone, a human growth hormone derivative, an animal growth hormone derivative, erythropoietin, calcitonin, interferon, interleukin, insulin and a colony stimulating factor.

Claim 27. (Amended) The composition as claimed in claim 24, wherein the active ingredient is a microorganism.

Claim 28. The composition as claimed in claim 27, wherein the microorganism is one or more of *Bifidus* or *Lactobacilli*.

Claim 29. (Amended) The composition as claimed in claim 22, wherein the active ingredient is an antidiarrhea agent.

Claim 30. (Amended) The composition as claimed in claim 22, wherein the active ingredient is a growth promotant.

Claim 31. (Amended) The composition as claimed in claim 22, wherein said composition comprises microparticles comprising a member selected from the group consisting of acrylate or derivatives thereof, albumin, alginates, carbomers, carrageenan, cellulose or derivatives thereof, dextran, dextrin, gelatin, polyvinylpyrrolidone and starch.

Claim 32. (Amended) The composition as claimed in claim 22, wherein said composition is in the form of an injection, as a

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*Alcant*  
sublingual tablet, as an oral tablet, as a sustained release  
sublingual tablet, microcapsules, pessaries, preconstituted  
solid dose for nasal spray, nasal drops, aqueous drops, eye  
wash, eye drops, skin washing solutions, or as a feed premix.

**REMARKS**

Claims 1-32 have been amended in order to remove improper  
multiple dependency and make the claims consistent with U.S.  
patent practice. Hence, the amendments to the claims do not  
constitute new matter, and entry is respectfully requested.

The Examiner is invited to contact the undersigned at his  
Washington telephone number on any questions which might arise.

Respectfully submitted,

  
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